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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/825,920      | 04/03/2001  | Ronald G. Udell      | 40524-SGTI          | 3656             |

25763 7590 11/16/2004

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| EXAMINER |
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WINSTON, RANDALL O

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| ART UNIT | PAPER NUMBER |
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1654

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/825,920

### Applicant(s)

UDELL ET AL.

### Examiner

Randall Winston

### Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 18-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Acknowledgement is made of the receipt and entry of the Request for Continued Examination (RCE) on 09/07/2004.

Claims 1-3 and 18 have been withdrawn from consideration and Claims 4-17 have been canceled.

New Claims 19-31 are under examination.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-31 are rejected under 35 U.S. 103(a) as being unpatentable over Matsuyama (US 6485760) in view of Hoffman (The Complete Illustrated Herbal, *Practical Herbalism, The Preparation of Herbs*, 1996, page 20-33), Mcpeak (US 6303586), LaGrone (US 6407068), Matsutani et al. (US 5552427), Shanmuyasundam et al. (US 5980902).

Applicant claims a soft gel capsule comprising rice bran oil, corosolic acid, yellow bee's wax, silica and extract of *Gymnenma sylvestre* in a mixture of claimed amounts.

Matsuyama teaches an oral composition for an increase in or lowering of blood sugar levels in a patient comprising a powdered herbal extract containing corosolic acid.

Matsuyama does not expressly teach that corosolic acid, rice bran oil, silica, yellow

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bee's wax and extract of *Gymnema sylvestre* are contained within a soft gel capsule as active ingredients therein or the claimed amounts administered to a human.

Hoffman beneficially teaches that the easiest way to take dry powdered herbs internally is to use soft gel capsules. (see, e.g., pages 20-33).

Mcpeak et al. beneficially teach rice bran oil (i.e. the rice bran is in liquid form) to control blood glucose levels. (see, e.g., column 7 lines 52-56).

LaGrone beneficially teach silica for the prevention of diabetes whereas silica would intrinsically control blood glucose levels when preventing diabetes. (see, e.g., column 4 lines 11-14).

Shanmyasundam et al. beneficially teach an extract of *Gymnema sylvestre* for controlling blood sugar to prevent obesity. (see, e.g., column 3 lines 16-20).

Matsutani et al. beneficially teach tablets were polished with yellow bees wax to give coated tablets. (see, e.g., column 20 lines 9-10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Matsuyama's oral powdered composition teachings to include Hoffman's beneficial oral soft gel teachings (note: the yellow bees wax taught by Matsutani is being utilized to coat the soft gel capsule) and also to include other beneficial teachings taught by Mcpeak, LaGrone, Shanmuyasumdam whereas Mcpeak, LaGrone, Shanmuyasumdam active ingredients are each being utilized for the maintaining or lowering of blood glucose levels in humans to obtain an improved claimed soft gel capsule composition for the administration of corosolic acid, rice bran oil, silica, yellow bee's wax, extract of *Gymnema sylvestre*, in a soft gel capsule for the

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maintaining or lowering blood sugar levels in humans. Furthermore, the adjustment of other conventional working conditions (e.g. the amount of corosolic acid contained within the soft gel capsule), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary

Please Note that patentability of a product (i.e. the claimed soft gel capsule) does not depend upon its method of production (i.e. heating the rice bran oil, continuously stirring the mixture, the corosolic acid is under a vacuum, the mixture is blended with nitrogen, the corosolic acid is produced by 1% Corosolic acid alcohol extracted from *Lagerstroemia Speciosa L.*). If the product in the product-by-process claim is the same as or obvious from a product of the prior art, then the claim is unpatentable even though the prior art product was made by a different process" (see, e.g. MPEP 2113).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
CHRISTOPHER R. TATE  
PRIMARY EXAMINER